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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/465,667 12/17/99 CEDGARD

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000530 HM22/0221
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EXAMINER

AFREMOVA, V

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED:

02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/406,667

Applicant(s)
Cedgard L.

Examiner
Vera Afremova

Group Art Unit
1651



☒ Responsive to communication(s) filed on Feb 5, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 11-28 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 11-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 09/029,336.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

DETAILED ACTION

Claims 11-28 are pending and under examination.

Information Disclosure Statement

The information disclosure statement filed 8/15/2000 partially fails to comply with the provisions of 37CFR 1.97, 1.98 and MPEP § 609 because copies of references AS, AT and AR are missing and/or no concise explanation of the relevance of the references AS, AT and AR was provided. The Form PTO-1449 filed 8/15/2000 has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claims 22-28 are objected to because of the following informalities: Latin names of lactic bacteria *Bifidobacterium animalis* and *Lactobacillus plantarum* have typing error in the species names. The Latin names of microorganisms should be italicized. And the genus names should be written without abbreviation at first occurrence in text of the claims. Appropriate correction is required.

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Claim Rejections - 35 U.S.C. § 112

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because it either lacks an antecedent basis for "fructose containing saccharides" or this claim is redundant.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,396,631 [A] taken with US 5,422,346 [B], US 5,531,989 [C], US 5,527,556 [D] and US 4,021,545 [E].

The claims are directed to a method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with fructose oligosaccharide or inulin and step of pressing the mixture into tablet. Some claims are/are further drawn to the use of particular species of lactic bacteria in the mixture such as *Lactobacillus bulgaricus*, *Lactobacillus plantarum*, *Streptococcus thermophilus* or *Bifidobacterium animalis*. Some claims are further drawn to incorporation of additives into the mixture such as starch or calcium diphosphate.

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US 4,396,631 teaches a method for method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with starch or other materials suitable for tablets and step of pressing the mixture into tablets or forming tablets. The cited patent discloses that the tablets with starch retained high viability of lactic bacteria after formation of tablets and during storage of tablets (col. 4, example 1). The cited method is lacking the disclosure of fructose oligosaccharide or inulin in the mixture intended for forming tablets.

US 5,422,346 discloses fructose oligosaccharide or inulin in the method for producing tablets and it teaches that inulin is compressed into tablets without the need of additional tableting material such as starch (col. 8, lines 41-44). The cited patent also teaches that inulin is a growth promoting substrate of lactic bacteria such as *Bifidobacterium sp* and that pathogenic bacteria can not utilize inulin unlike beneficial bacteria in the gut of animals (col. 18, lines 25-37).

US 5,531,989 teaches method for producing dry mixture in powder form comprising 40-60 % by weight of inulin and/or fructose oligosaccharide and 0.1-20% by weight of lactic bacteria of *Lactobacillus sp.* and /or *Bifidobacterium sp.* including *L. bulgaricus* and *L. plantarum* (col. 13, lines 38-50 and col. 4, lines 1-30).

US 5,527,556 teaches method for producing semi-solid inulin products with live lactic bacteria in a form of cream (col.14, example 13) or paste and it teaches that incorporation of inulin makes possible to stabilize water and the resulting composition has viscosity which allows to ^{or}from tablets (col.15, line 35).

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US 4,021, 545 teaches a method for producing tablets comprising inulin and other additives such as starch or calcium diphosphate (col.5, example 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate inulin of the secondary references into lactic bacteria and/or bifidobacteria containing tablets in the method of US 4,396,631 with a reasonable expectation of success in obtaining tablets with beneficial effects with regard to promoting growth of beneficial lactic or bifidobacteria and suppressing growth of pathogenic bacteria as suggested by US 5,422,346 and as taught by US 5,531,989. Or it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin of the secondary references for starch in the lactic bacteria and/or bifidobacteria containing tablets in the method of US 4,396,631 with a reasonable expectation of success in obtaining pressed or compresses tablets since the use of inulin allows for the exclusion of additional tableting binder such as starch, for example, as taught by US 5,422,346. In addition, the cited US 5,527,556 also teaches a superior viscosity of the inulin containing semi-solid mixture if intended for tableting. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Art Unit:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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February 20 2001.


FRANCISCO PRATS
PRIMARY EXAMINER